



2000-2002 STATE HEALTH PLAN ANNUAL REPORT

V. CERTIFICATE OF NEED

Overview: Section five provides information relevant to Volume Two of the State Health Plan which will contain certificate of need standards that have been reviewed and possibly revised. A summary of recent regulatory changes impacting the Certificate of Need program and a discussion of the revised certificate of need standards are presented.

Summary of Regulatory Changes

Certificate of Need (CON) programs are often associated with cost containment measures. Additionally, the Legislative findings in the CON law declare the need for health services to be provided in an orderly, economical manner that discourages unnecessary duplication.

Although some states have repealed their CON statutes, thirty-six (36) states and the District of Columbia retain some form of review. Three states limit their review to long-term care. The structure of the programs varies widely, with some states using other regulatory mechanisms instead of or in conjunction with CON programs.

In West Virginia, all health care providers, unless otherwise exempt, must obtain a CON before (1) adding or expanding health care services, (2) exceeding the capital expenditure threshold of \$2,000,000, (3) obtaining major medical equipment valued at \$2,000,000 or more, or (4) developing or acquiring new health care facilities.

The statutorily mandated CON review process primarily includes the determination of need, consistency with the State Health Plan, and financial feasibility. Need is determined using CON Standards, which generally include population-based quantifiable need methodologies. Financial feasibility includes the evaluation of the reasonableness of proposed charges to patients and the determination as to whether the expense and revenue projections demonstrate fiscal viability for the proposed project. Other review criteria include quality, accessibility, and continuum of care.

Certificate of Need programs are noted for being effective in encouraging the rational distribution of health care services, particularly by limiting purchases of new technology. States that have eliminated CON programs report that expensive new technology is purchased as soon as it is available, while states retaining their CON programs report being able to control costs and placement by delaying purchases until lower cost and more efficient generations of the technology are available.¹

The advantage of CON programs to the public is that they encourage accountability by providing an avenue for public comment, discourage or limit unnecessary services, and promote community planning. In West Virginia, the CON program offers some protection for small, often financially fragile, rural hospitals and the underinsured population they serve by promoting the availability and accessibility of services and, to some extent, the financial viability of the facility.

¹ Arthur Clark Company, "Certificate of Need Study," September 1998, p. 11–13. Jim Nathan, "Community Hospitals and Health Systems Certificate of Need (CON) White Paper," May 1998, <<http://www.communityhospitals.org/chhscon.html>> (January 7, 2000).

Mandated Certificate of Need Study

During its 1997 session, the West Virginia Legislature directed the Health Care Authority to conduct a study of the Certificate of Need (CON) program. The study was to address the following:

- The effects of any changes in the CON program on managed care and access for uninsured and rural consumers
- Recommendations concerning which health services or capital expenditure levels should be exempt and why
- The status of similar programs in other states

As a result of that study the following recommendations were made:

1. Increase the capital expenditure minimum to \$2,000,000
2. Limit the scope of review for new services to a list of 23 specific services that would be identified in regulation
3. Eliminate the exemption for facilities and services developed by HMOs
4. A “fast track” process for review of projects not involving direct patient care should be established
5. The retention of a modified and less restrictive program was recommended versus elimination of the program

The Legislature accepted the recommendations and amended pertinent sections of the law and approved regulations to effectuate these changes, which were implemented beginning July 1, 2000. In the 1999 session, the West Virginia Legislature passed two bills affecting the Certificate of Need program. First, Senate Bill 492 increased the capital expenditure threshold from \$1 million to \$2 million and increased the threshold for major medical equipment from \$750,000 to \$2 million. West Virginia Code §§16-2D-2(h) and Senate Bill 492 also required the Authority, under W. Va. §16-2D-3(b)(5), to specify a list of services subject to Certificate of Need review. The Certificate of Need

study group recommended a list comprised of twenty-three (23) health services, which have been promulgated by the Authority in regulation at 65 C.S.R. §7 and approved by the Legislature in the 2000 session. Second, Senate Bill 550 amended W. Va. §16-2D-5(a), which relates to the conversion of excess acute care beds to distinct part skilled nursing beds for hospitals meeting certain criteria.

In the 2000 session, no new substantive legislative changes were made to the Certificate of Need program or other programs or activities associated with the Authority.

Revision of Certificate of Need Standards

The Authority has begun the process of reviewing and making any changes necessary to the certificate of need (CON) standards which will later comprise Volume Two of the 2000-2002 State Health Plan. Due to the delay in the passage of changes to W. Va. C.S.R. §65-7, the process has been delayed several months.

West Virginia Code §16-2D-5(l)(1) states that the state agency (the Authority) shall coordinate the collection of information needed to allow the state agency to develop recommended modifications to the CON standards, and file with the Secretary of State, for publication in the state register, a notice of proposed action, including the text of all proposed amendments and modifications, and a date, time and place for receipt of general public comment. The Authority may hold a public hearing or schedule a public comment period for the receipt of written statements or documents.

W. Va. Code §16-2D-5(l)(2) requires all proposed amendments and modifications, including a record of the public hearing or written statements and documents received pursuant to a public comment period, be presented to the Governor. Within thirty days of receiving the proposed amendments or modifications, the Governor shall either approve or disapprove all or part of the amendments and modifications.

West Virginia Code 16-2D-5(b) requires the Authority to specify by rule those health services subject to certificate of need (CON) as recommended by the CON study conducted pursuant to W. Va. Code §16-29B-19(a). These health services were listed in changes to W. Va. C.S.R. §65-7.

West Virginia Code §16-2D-5(b) also requires the Authority to make any necessary amendments or modifications to the CON standards within a three year period from the effective date of W. Va. Code §16-2D-5(b), which was June 11, 1999.

In order to effectively review the CON standards for possible revision within the required timeframe the Authority has developed a plan to review the CON standards in several phases. For each phase, the Authority *may* form task forces, comprised of representatives of consumers, business, providers, payers and state agencies, to assist in making necessary revisions.

Following the presentation to the task force, if formed, and after making any changes that may be appropriate, the proposed CON standards will be filed with the Secretary of State and will be open for a thirty-day public comment period. After the public comment period has closed, and after making any needed changes, the proposed CON standards will then be forwarded to the Governor for review.

The services selected for review/change of CON standards are those health services recommended by the CON study conducted pursuant to W.Va. Code §16-29B-19(a). The list of health services set forth in W.Va. C.S.R. §65-7-28.1 and the proposed schedule by phases are listed below. The standards in bold have been or are being reviewed.

Certificate of Need Standards Schedule

Phase 1	Long-term Acute Care Hospitals (LTACH)
Phase 2	Cardiac catheterization
	Open-heart Surgery
Phase 3	Behavioral Health/Developmental Disabilities ICF/MR Outpatient Behavioral Health Services
Phase 4	Home Health Services Hospice Services In-Home Personal Care Services
Phase 5	Ambulatory Care Centers Ambulatory surgical facilities/centers Diagnostic services
	Birth Centers
Phase 6	Megavoltage Radiation Therapy Services (MRT) Fixed Magnetic Resonance Imaging Services (MRI) Positron Emission Tomography (PET) Lithotripsy Services
Phase 7	End Stage Renal Disease and Home Training
Phase 8	Inpatient Services Discrete alcohol, drug treatment and rehabilitation Comprehensive medical rehabilitation Discrete long-term care nursing beds Addition of Acute Care Beds Medical or surgical beds Discrete Obstetrical units Discrete Pediatric units Discrete Psychiatric units Special care units (Burn, ICU, CCU, NICU, PICU, etc.)
	Surgical Services Services Operating rooms
Phase 9	Organ and Tissue Transplants Emerging Technology

In order to collect the information needed to develop modifications to the CON standards, the Authority may require providers to submit survey information on the listed services.

Because the Authority will be gathering needed information on several services simultaneously, standards for a service listed under Phase 5 may be completed before standards for a service listed under Phase 3. In all cases, if the necessary work has been completed, the proposed CON standard will be presented for approval.

In addition to the services listed above, the Authority may develop/revise CON standards for other “new institutional health services” set forth in W.Va. Code §16-2D-3.

The particular standards revised and the date such standards went into effect after being approved by the Governor are as follows: Lithotripsy Services (effective July 7, 2000); Positron Emission Tomography (effective July 7, 2000); Addition of Acute Care Beds (effective July 10, 2000); and Cardiac Catheterization (effective December 22, 2000).² These revised standards may be found on the WVHCA website (<http://www.hcawv.org>).

A study commissioned by the Authority entitled “Nursing Facility Bed Supply and Need” can also be found on the WVHCA website. This study was presented to the Legislative Oversight Commission on Health and Human Resources Accountability in October 2000 fulfilling the Authority’s statutory duty to study the need for nursing facility beds in the state.

² A revision of the Open-Heart standards was submitted, but was not approved by the Governor. As a result, the standards developed in 1992 remain in use.